## Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Thus, claim 1 has been amended to recite that the 4-(2-methyl-1-imidazolyl)-2,2-diphenylbutylamide or a medically acceptable salt thereof is the sole active ingredient in the transdermal preparation. Support for this is found in the use of the word "alone" at page 10, line 1, along with the fact that all of the working examples of the invention as set forth in the specification contain only this compound as the sole active ingredient.

Claims 8-9, 11 and 13 have been amended to be consistent with amended claim 1.

The provisional rejection of claims 1, 4-9, 11 and 13 for obviousness-type double patenting as being unpatentable over claims 1-20 of Serial No. 11/815,499 is respectfully traversed.

In general, it is not always true that, when an oral preparation of a drug is known, a transdermal preparation of such a drug is easily achieved. The essential feature of the present invention resides in that a transdermal preparation of 4-(2-methyl-1-imidazolyl)-2,2-diphenylbutylamide (hereinafter, referred to as "KRP-197") is produced for the first time.

In contrast, the essential features of the invention of Serial No. 11/815,499, in particular as clearly understood from its claims 19 and 20, are as follows:

(i) The composition of the transdermal preparation is limited (including an adhesive, liquid paraffin, N-methyl-2-pyrrolidone and/or propylene glycol, and oleic acid);

(ii) The amounts of these components are limited; and

(iii) The amount of KRP-197 and the size and thickness of the resulting transdermal preparation are limited to particular values.

By configuring the transdermal preparation in a manner satisfying the above items (i) to (iii), the transdermal preparation containing KRP-197 can maintain a certain effective blood drug level over a certain period of time.

Since the object of the invention of Serial No. 11/815,499 is different from that of the present invention, and the essential features of Serial No. 11/815,499 are distinguished from those of the present invention, Applicants respectfully submit the rejection on the ground of obviousness-type double patenting should be withdrawn.

The patentabilty of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 1, 4-9 and 11 under 35 U.S.C. § 103(a) as being unpatentable over Miyachi et al. in view of Nitti and further in view of Versi or Landau et al. is respectfully traversed. [In presenting this rejection in item 6 toward the bottom of page 4 of the Office Action, the Examiner refers to the Versi reference as US 2003/0190072; but it is Applicants' understanding that the Examiner meant to refer to US 2003/0191172 as correctly cited on the PTO-892 form attached to the Office Action.]

As the Examiner has noted, Miyachi et al. do not suggest a transdermal preparation like those of the present invention. In general, the production of pharmaceutical products in the form of transdermal preparations are not achieved only based on the level of the biological activity of the compound contained therein as an active ingredient. Specifically, the achievement of such production can be significantly varied by the stability of the compound in external patches, the permeability of the compound through skin, the irritancy of the preparation, and the like. In other words, even if the activity of KRP-197 is larger than oxybutynin, it is uncertain whether the compound is effectively utilized in transdermal preparations as pharmaceutical drugs.

The invention of Versi relates to a method for the treatment or prophylaxis of a urinary incontinence condition by administering a cyclooxygenase inhibitor alone or in combination with an anticholinergic drug.

The invention of Landau et al. relates to a method of treating a symptom of a lower urinary tract disorder by administering a compound that has 5-HT3 receptor antagonist activity and NorAdrenaline Reuptake Inhibitor (NARI) activity. The reference simply discloses that an anticholinergic drug may be co-administered.

Furthermore, both the Versi and Landau et al. references simply list KRP-197 as one example of known anticholinergic drugs. Accordingly, they do not suggest whether KRP-197 contained in transdermal preparations is actually effective. As discussed above, whether the compound is effectively utilized in transdermal preparations as pharmaceutical drugs depends on various factors other than its biological activity. Accordingly, the simple disclosure as one

exemplary anticholinergic drug would not motivate one skilled in the art to use it in a transdermal preparation.

Accordingly, the Versi and Landau et al. references, taken with Miyachi et al., do not disclose or suggest the transdermal preparation including KRP-197 as the sole active ingredient, which is defined by the presently amended claims.

Nitti generally discusses transdermal therapy as compared to oral therapy for overactive bladder, but considering the deficiencies of the other references as discussed above, Applicants take the position that even if Nitti were combined with these other references, the result would still not suggest the presently claimed invention.

The rejection of claim 13 under 35 U.S.C. § 103(a) as being unpatentable over Miyachi et al. in view of Nitti and either Versi or Landau et al. and further in view of Luo et al. is respectfully traversed.

The comments set forth above concerning the Miyachi et al., Nitti, Versi and Landau et al. references are equally applicable to this rejection.

The Examiner applies the Luo et al. reference for the structure of the transdermal device of claim 13. But since claim 13 is indirectly dependent on claim 1, which is patentable over the other references for the reasons discussed above, it is apparent that even if the references were combined in the manner suggested by the Examiner, the result would still not suggest the subject matter of claim 13.

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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July 19, 2010